



CHARLES H. CHEVALIER
Director

Gibbons P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Direct: (973) 596-4611 Fax: (973) 639-6263
cchevalier@gibbonslaw.com

April 5, 2024

VIA ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J.
United States District Court District of New Jersey
Clarkson S. Fisher Federal Building And United
States Courthouse
402 E State St.
Trenton, New Jersey 08608

**Re: *AstraZeneca Pharm. LP v. Natco Pharma Ltd.*, Civil Action No. 3:23-796 (RK) (TJB);
AstraZeneca Pharm. LP v. Sandoz Inc., Civil Action No. 3:24-641 (RK) (TJB)
(CONSOLIDATED)**

Dear Judge Bongiovanni:

Our firm, together with Williams & Connolly LLP, represents Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH ("Plaintiffs") in the above-referenced matters. With Midlige Richter, LLC and Rakoczy Molino Mazzochi Siwik LLP, counsel for Defendants Natco Pharma Ltd. and Natco Pharma, Inc. (together, "Natco"), and with Hill Wallack LLP and Crowell & Moring LLP, counsel for Defendant Sandoz Inc. ("Sandoz") (Natco and Sandoz, together, "Defendants"), we jointly submit the attached Amended Scheduling Order and the attached Supplemental Stipulated Confidentiality Order for the Court's consideration.

The parties have been able to reach agreement on all but one issue related to this proposed schedule and confidentiality order. The parties have come to an impasse on one issue in paragraph 27 of the Supplemental Stipulated Confidentiality Order, which concerns the cross-use of Natco's and Sandoz's respective confidential information. The parties have included in paragraph 27 their respective proposed language for the Court's consideration. The parties set out their respective arguments in brief below.

I. Plaintiffs' Position Statement

The parties agree that these cases share many overlapping issues, including all issues relating to the validity of two patents, No. 7,449,464 and 8,859,562, that have been asserted against both Defendants. To the extent that there are documents that are relevant to the common issues in this case, they should be able to be confidentially shared among the lawyers under the Confidentiality Order, and submitted to the Court, under seal, as relevant in pleadings or at trial, regardless of the original source of those documents. Plaintiffs' proposed Paragraph 27 achieves that goal and is most efficient for the Court and the parties, while still safeguarding the reasonable confidentiality interests of the Defendants.

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Similar “cross-use” provisions to that proposed by Plaintiffs are common in cases like this one involving claims of patent infringement brought under the Hatch-Waxman Act, where courts recognize that common issues predominate over individual issues. *See, e.g., Theravance Biopharma v. Eugia Pharma*, No. 23-cv-926-KMW-AMD, Dkt. No. 179, Ex. A at ¶ 41 (D.N.J. Jan. 12, 2024); *Aerie Pharms. v. Micro Labs*, No. 22-cv-1365-GC-LHG, Dkt. No. 38, Ex. B at ¶ 49 (D.N.J. Oct. 14, 2022); *see also Novartis v. Aurobindo*, No. 20-1426-LPS, Dkt. No. 42, Ex. C at ¶ 12.4 (D. Del. Sep. 21, 2021); *Pfizer v. Aizant*, No. 19-cv-743-CFC, Dkt. No. 65, Ex. D at 14–15 (D. Del. Dec. 9, 2019). By contrast, courts have rejected prohibitions like those Defendants propose due to the attendant inefficiency. *See Pharmacyclics v. Fresenius Kabi*, No. 18-cv-192-CFC-CJB, Oral Order, Ex. E (D. Del. Oct. 18, 2018); *see also Shire v. CorePharma*, No. 14-cv-5694-RMB-JS, Dkt. No. 62, Ex. F at 27:1–31:9 (D.N.J. May 21, 2015).

Defendants’ proposal imposes significant burdens on the parties and the Court. Under Defendants’ proposal, any time Plaintiffs want to use a Defendant-produced document relating to a common issue in a confidential pleading, expert report, hearing, or trial, Plaintiffs would be forced to either seek prior authorization for that use with the individual defendant (with the attendant prejudice of previewing Plaintiffs’ case in advance of the hearing or submission and with no guarantee that the Defendant would consent) or to approach the Court. This approach invites inefficient seriatim disputes and would needlessly burden the Court.

With respect to consolidation, Defendants are asking to have their cake and eat it too. Defendants are able to pool resources to litigate the case and, to the extent they believe their confidential information supports their position, they can share that information without consulting Plaintiffs. If Defendants’ confidential information supports Plaintiffs’ position, however, Plaintiffs will be forced to jump through hoops by obtaining advance permission to use the documents or seeking the Court’s intervention every time Plaintiffs want to use a Defendant’s confidential information.

Moreover, Defendants’ reasonable interest in confidentiality is protected by the other provisions of the Confidentiality Order, which restrict disclosure to outside counsel and a handful of in-house personnel (¶ 6.2) and impose a strict two-year bar, not just on use of the information, but on patent prosecution and competitive decision-making generally (¶ 5.4). Defendants have raised no concern as to the sufficiency of these protections or the other additional ones in the Confidentiality Order. Instead, Defendants appear to be seeking a litigation advantage in the guise of the Confidentiality Order via an advance look at any of Plaintiffs’ arguments that rely on Defendants’ documents. That should not be condoned and the Court should adopt Plaintiffs’ proposed language.

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II. Natco and Sandoz's Position Statement

Defendants respectfully request that the Court restrict Plaintiffs' ability to share one Defendant's confidential information with the other Defendant, absent the producing party's consent.

Natco and Sandoz are direct competitors in the highly competitive generic pharmaceutical market. It is crucial that each Defendant be able to decide for itself what confidential information to share with its generic competitors and their legal representatives. This is especially true of highly proprietary information relating to each Defendant's ANDA product, including specific details regarding product formulation, status of FDA review and approval, and marketing plans. Defendants have each produced or may produce this type of information to Plaintiffs as part of discovery, but they have no plans to share it with each other, even among outside counsel.

However, under Plaintiffs' proposal, the breadth of which extends to *all* documents and issues, Plaintiffs—who asked Defendants to agree to consolidation—would be free to indiscriminately share one Defendant's confidential information with the other Defendant, including that Defendant's outside counsel, in-house counsel/representatives, experts, and consultants. This would directly undermine each Defendant's ability to control its most sensitive commercial information and could directly and irreparably harm Defendants in the process.

Defendants' proposal does not burden or prejudice Plaintiffs in any way. First, Plaintiffs have identified no specific need to disclose such information between Defendants. That makes sense, because one Defendant's confidential information is irrelevant to claims and defenses related to the other Defendant. Second, Defendants' proposal does not restrict Plaintiffs' ability to *use* any confidential information if otherwise permitted by the agreed confidentiality order. At most, it would require Plaintiffs to redact one Defendant's confidential information before sending a document to the other Defendant or seek Defendants' consent before sharing the unredacted confidential information. That is a minimal burden in this case with only two Defendant Groups, particularly when compared to the significant competitive harm that could occur from improper disclosure of Defendants' competitive information. Finally, Defendants' proposal does not preclude Plaintiffs from applying to the Court if in the future they contend there is a crucial need to share one Defendant's information with the other and the Defendants do not provide consent to share this information. Defendants intend to be reasonable with any such requests for consent.

It should be up to Defendants—not Plaintiffs—to decide whether and to what degree their own confidential information is disclosed to their direct competitors. Courts in this district have repeatedly recognized the importance of a defendant's control over disclosure of its own confidential information among direct competitors in the Hatch-Waxman context by entering protective orders with similar restrictions on the plaintiff disclosing one defendant's confidential information to another defendant as sought by Defendants here. *See, e.g., In re Fetzima*, No. 17-cv-10230, ECF Nos. 59, 67 (D.N.J. 2018) (Ex. 1); *Supernus Pharm. Inc. v. Actavis, Inc.*, No. 14-

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cv-6102, ECF Nos. 62, 77 (D.N.J. 2015) (Ex. 2); *Jazz Pharm., Inc. v. Amneal Pharm., LLC.*, No. 13-cv-391, ECF Nos. 138, 142 (D.N.J. 2015) (Ex. 3). Notably, this protection against cross-use was applied in these cases notwithstanding other protections in the protective orders. This case should be no different.

In light of the above the parties would like to proceed with the teleconference currently scheduled for April 22, 2024, and will be prepared to discuss the issue in paragraph 27 of the Supplemental Stipulated Confidentiality Order. We thank the Court for its consideration and assistance.

Respectfully submitted,

s/ Charles H. Chevalier
Charles H. Chevalier

Attachments

cc: All counsel of record (via ECF)